

REMARKS/ARGUMENTS

Claims 39-48, 52-59, 65-69, 76-80 are presently pending in the application.

Regarding the objection to the drawings under 37 C.F.R. 1.83(a) at the top of page 2 of the Office Action, Applicants note that this objection was first imposed, identically-worded, in the Office Action dated September 13, 2005, responsive to which Applicants submitted a replacement drawing page showing an imager adapted to provide an image of a user and further showing an infrared imaging device. The December 20, 2006 Office Action appeared to accept the substance of the replacement drawing page but required that elements in the drawing be labeled with indicia denoting or connoting their function, responsive to which Applicants submitted a second replacement drawing page with the requested indicia. The following Office Actions of July 13, 2007 and April 1, 2008 apparently accepted the second replacement drawing sheet, as it was not critiqued or objected to in any way.

The outstanding Office Action states, on page 3, that “applicants have deliberately chosen to remove the reference to provisional application 60/064,465 from the specification...,” but this removal from the first paragraph of the specification was submitted only after the Examiner had objected to Applicants’ first paragraph in about three or four consecutive Office Actions without providing what Applicants regard, with all due respect, to be a clear reason for the objections. For example, the Office Action’s repeated language that “the presumption and assertion that the priority of 60/064,465 is inherent” is considered unclear to Applicants. The perhaps non-optimal wording accounts for why almost every one of Applicants’ responses to the objection did something different. If Applicants’ phone calls would have been returned or if Applicants would have received a more responsive or situation-tailored explanation on what in the first paragraph of the specification was objectionable, the deletion would not have occurred. With this Amendment, Applicants retract that deletion and reintroduce the prior language that U.S. Application No. 09/188,072 claims the benefit of, and incorporates by reference the contents of, U.S. Provisional Application No. 60/064,465.

Regarding the statement at the bottom of page 3 of the Office Action that “these determinations ... are now considered prior art,” Applicants disagree and submit that such is not the case. Applicants have not admitted any of the mentioned

determinations to be or as containing prior art. The Office Action asserts that a traversal by Applicants of a determination must be seasonably made and must be adequate the failure of either of which justifies the Examiner to state that the determination is “taken” to be admitted prior art. However, the Examiner’s taking, or interpreting, his prior determination to be admitted prior art does not make that determination non-traversable. Thus, Applicants respectfully traverse each of the Examiner’s determinations, even to the extent they have already been “taken,” and Applicants iterate clearly for the record that these determinations made by the Examiner are challenged, traversed, and by no means admitted by the Applicants to be prior art. Applicants request that, for each determination, the Examiner kindly provide a combinable reference that would be considered by one skilled in the art at the time of the invention to teach and to provide motivation for such determination to meet the currently claimed invention, for a clear record and betterment of Applicants understanding thereof for traversal.

Claims 39-46, 48, 52, 53, 65-68, 76, 77, 79 and 80 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Rizoïu et al. (International Publication No. WO97/07928) in combination with Paolini et al. (U.S. Patent No. 6,206,873), Massengill (U.S. Patent No. 6,106,516), and allegedly “admitted prior art of ... removal of fat ... sterile fluids ... plastics ... and ... steel”; and claims 47, 54-59, 69 and 78 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Rizoïu et al. in combination with Paolini et al., Massengill, and allegedly “admitted prior art of ... removal of fat ... sterile fluids ... plastics ... and ... steel” as applied to claims 39-46, 48, 52, 53, 65-68, 76, 77, 79 and 80 and further in view of Kittrell et al. (U.S. Patent No. 4,913,142). These rejections are respectfully traversed.

Applicants’ independent claims contain combinations of characteristics connoting architectures and arrangements adapted for tunneling through cartilage and, especially, hard tissue (e.g., bone). To the extent recitations of such uses are not specifically included in the claims, then need not be, as the claimed structures are not anticipated and not obvious even without such inclusion.

Consistent with these uses, the inventive cannulas do not need to possess a leading tip that is shaped to pierce, cut, or disrupt the tissue, and, instead, according to a preferred implementation, the laser and fluid can do at least part, and, in typical applications, substantially all, of the cutting, with the cannula distal end emitting such

items (the laser and fluid) to effectuate tunneling of the device through cartilage and hard tissue. Figures 9b and 11b of the current application contain images of preferred blunt-tip implementations of Applicants' invention for laser-cutting, e.g., connective tissue.

For such hard or semi-hard tissue procedures, the positioning of Applicants' interaction zone off-axis to the central (longitudinal) axis of the cannula, when combined with rotation of the cannula about the axis during the tunneling, allows for generation of a "tunnel" sufficiently sized in width to allow the cannula to be advanced/navigated therethrough/therein to an operable, or even optimal, degree.

The Paolini disclosure, on the other hand, is not concerned with (a) laser-cutting, or (b) tunneling through cartilage or bone, since its disclosure is limited to lipolysis applications. With reference to lines 14 and 15 of Paoline, the lipolysis is described as being performed subcutaneously rather than under cartilage or bone, for aesthetic treatments. Line 24 of column 2 of Paoline classifies its lipolysis procedures as accomplishing liposuction.

The Office Action states that Paolini can be used "for removal of fat tissue in joints" but Applicants do not agree and, furthermore, do not see where the Examiner has obtained support for such assertion. Applicants request that the Examiner kindly provide a combinable reference that would be considered by one skilled in the art at the time of the invention to teach and to provide motivation for such a use to meet the currently claimed invention.

The Paolini disclosure specifically teaches away from laser-cutting connective tissue by iterating that its laser is for lipolysis (see column 3, lines 31-34, 49-53 and 61-67; column 4, lines 4-6, 8-10, 16-22, 26-29, etc.).

Paolini appears to distinguish its invention from prior art devices on the precise point of it not cutting or damaging collagen.

The Paolini laser does not intend to and indeed apparently cannot cut collagen (see column 1, lines 60-63 "maintains collagen... substantially unaltered or undamaged"; column 2, lines 18-21 "the most important aspect...is the fact that the collagen fibers remain intact...very important"; column 2, lines 18-21 "collagen fibers ... are not damaged...and remain intact"; lines 3, lines 34-37 "intensity and wavelength of the laser...maintains collagen...substantially unaltered..."). It does not seem coincidental that the Paolini laser settings are not suitable, e.g., too low, to effectuate such cutting.

Paolini contains no teaching, suggestion, or even hint, of its laser performing piercing of or tunneling through cartilage or bone, which contexts are among those highlighting the advantageous off-axis feature of the currently claimed invention.

An interpretation that “Paolini et al envision the laser doing the...cutting,” such as occurring on page 4 of the Office Action, is misplaced and more likely than not distortedly based on hindsight. The Office Action characterized Paolini’s claim 4 recitation, of “said piercing” being performed with a needle, as broadening the Paolini disclosure to piercings being performed with a laser. However, as explained above, Paolini’s laser is limited to settings that cannot, and do not, cut skin.

The recitation in claim 4 of a “sharp edge” does not broaden claim 1 to piercing with “lasers,” since the piercing of claim 1 could be performed, instead of with the sharp edge of a needle, with, for example: a blade-like member (column 3, line 29 “beveled end” not necessarily “sharp”); a scalpel; a non-laser/non-needle laparoscopic tissue-entry device, a non-laser/non-needle liposuction tissue-entry device; or the “point” rather than sharpened edge of a needle (column 3, line 31, 41 and 54 “point”; column 4, line 16 “pierce”). Thus, the mere fact that the claim 1 “piercing” term may be performed by something other than a “sharp edge” does not mean that claim 1 discloses or teaches piercing by a laser. It is noted that blade-like members, scalpels, non-laser/non-needle laparoscopic tissue-entry devices, non-laser/non-needle liposuction tissue-entry devices; and needle “points” are not specifically excluded from disrupting the collagen (such as collagen of skin) of the patient, but that the Paolini laser is.

Applicants respectfully disagree with the Examiner’s requirement for some type of showing (e.g., of criticality) in connection with the presently claimed structure, which includes, among other things, an interaction zone positioned off-axis to the central (longitudinal) axis of the cannula. As for an advantage, the Applicants determined, and, accordingly, designed, the architecture of the currently-claimed device to have an interaction zone positioned off-axis to the central axis of the cannula so that during tunneling through, for example, cartilage or hard tissue such as bone the cannula can be rotated about its axis to generate a “tunnel” sufficiently sized (e.g., enlarged) in width to allow the cannula to be advanced, or to be more easily advanced, therethrough, or to be navigated, or more easily navigated, during or after the tunneling process.

As presently presented, the independent claims in this application recite, for example, “the transmitter axis being (a) non-identical to, (b) non-overlapping with

and (c) closer to the inner wall surface than the cannula axis” (claim 54), “the transmitter axis being disposed closer to the inner wall surface than to the cannula axis” (claim 65), and “a transmitter axis positioned closer to the inner wall surface than the cannula axis” (claim 66).

It is respectfully submitted that the current independent claims are neither anticipated by nor obvious in view of the prior art of record, and thus are allowable over the prior art of record. It is submitted that each of the presently pending dependent claims is allowable at least because of its dependency upon an independent claim, and further because of the additional limitations recited therein.

Reconsideration and withdrawal of the rejections under 35 U.S.C. 103(a) is respectfully requested.

Applicants submit that the application is now in condition for allowance, and an early indication of same is requested.

Should the Examiner believe that a telephone conference with Applicants’ representative would be helpful to advance the prosecution of the application, or for any other reason, he or she is kindly invited to contact the undersigned with any questions.

The Commissioner is hereby authorized to charge any needed fees to deposit account 50-1600.

Respectfully submitted,



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